b.) Remarks

Claims 1-27 and 29-64 are pending in this application. Claims 4, 26, 36, 51, and 59 have been amended in various particulars as indicated hereinabove. Claim 28 has been canceled.

Turning to the merits, a review might be helpful to understanding the patentability of the present invention, the embodiments described in the specification, and their prior art context.

A number of different techniques allow for the analysis of the inner walls of blood vessels. One example is optical coherence tomography (OCT). The coherence of light sources in conjunction with interferometer systems are used to analyze the three-dimensional structure of the inner walls of the arteries, often to find regions that could give rise to a heart attack or other vascular obstruction.

Another approach to the analysis of blood vessels uses spectroscopic analysis of those blood vessels. In one example, the near infrared spectroscopic response of the blood vessels is analyzed to determine the chemical composition of those blood vessels, which information is used determine the state of the blood vessels.

In OCT, balloons are commonly used to obstruct the blood flow at the point of analysis. This creates a void that the optical probe can then exploit to assess the three-dimensional structure of the blood vessel walls.

In some spectroscopic approaches, this complete obstruction of the blood flow is not necessary because the wavelength of operation of these systems is selected such that there is good penetration through the blood, or other intervening fluid. Chemometric analysis can further be exploited to remove noise associated with the intervening blood.

Since a balloon is not used to evacuate and block blood, spectroscopic analysis is often much more comfortable to the patient with a lower risk of mortality. A problem arises, however, in that the position of the probe relative to the wall of the blood vessels

is not known and the probe position can be influenced by the pulsatile flow of the blood around the probe.

The present invention is directed to techniques for dealing with this uncertainty as to the physical relationship between the probe and the vessel wall. Specifically, in one example, the optical signals collected by the probe are analyzed in order to determine this mechanical relationship. When the mechanical relationship is appropriate for the analysis of the blood vessels, then the signals are used to perform that analysis. In another example, the probe head is actually shaped to interact with the flowing blood in order to create a desired mechanical relationship between the probe head and the vessels walls. This relationship can happen either at specific points during the cardiac cycle due to the pulsatile nature of the blood flow or continuously in other potential embodiments.

Turning to the rejections, claims 1-64 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/426,750. This rejection is respectfully traversed for the following reasons.

Deferment of this issue is requested until patentable matter is identified in either or both of the applications.

Nonetheless, it is important to point out that none of the claims in the applied 10/426,750 application require the use of the optical signals to determine the mechanical relationship between the probe and the vessel walls and specifically use the optical signals to determined when the analysis of the blood vessels is performed. Thus, it is believed that the present claims are distinguishable over the claims in the 10/426,750 patent.

Claims 1-6, 11-13, 19-21, 23-33, 39-41, 47, 48, and 50-64 were rejected under 35 U.S.C. 102(b) as being anticipated by Auer *et al.* (US Patent No. 5,383,467). This rejection is respectfully traversed for the following reasons.

Each of the independent claims is distinguishable over the applied reference.

Claim 1, for example, requires the combination of analyzing the optical signals to determine whether the probe is close enough to the vessel walls to enable assessment and then using the received optical signals for that assessment when the probe is determined to be positioned accordingly.

It must be appreciated that the applied Auer patent is directed to an OCT system, and as such, is used to determine the specific mechanical relationship between the probe and the vessel walls. In fact, such systems can actually create three-dimensional images of those walls. For example, the following section, cited in the pending Action, from column 4 of the Auer Patent, describes the common OCT functionality:

> In the operation of the device of FIG. 1, a beam of reflected energy is returned from tissue mass 28 by operation of catheter 15 and fiber coupler 18. This reflected beam is then presented to beam splitter 12. In addition, a reference beam is reflected from mirror 17. This beam is also presented to beam splitter 12. These two beams, one beam being an X position reference beam and the other a beam containing information relative to tissue mass 28 for the present Z position of distal end 27, combine or interfere at beam splitter 12. As a result, an interference pattern beam 30 (i.e., an output beam) is presented to photodetector 31. The output of detector 31 is presented as a second input to signal detector 24. The output from signal detector 24 is provided as an additional input to computer 21. Computer 21 operates to drive a display output 35 whereat the X-Y plane configuration of vessel 26 is displayed, and wherein the amplitude of the interference signal is plotted as the Y coordinate, and as a variable function of the X position of the catheter's distal end 27 within vessel 26.

Nonetheless, the distance assessment in the Auer OCT system is not used to trigger an assessment of the vessel walls when a specific mechanical relationship between the probe and the vessel walls is determined. Instead, the distance relationship is the assessment itself.

In a similar vein, the applied reference does not suggest "initiating diagnosis or treatment of the vessel walls in response to analyzing the optical signals if the probe is determined to be close enough to the vessel walls to enable the diagnosis or treatment" as required by claim 26.

Claim 59 requires analyzing the optical signals that are indicative of the spectral response of the vessel walls. The Auer patent does not generate a spectral response of the vessel walls, but instead determines distance information to the vessel walls.

Finally, claim 61 requires "using the received optical signals to assess the vessel walls when the probe is determined to be close enough to the vessel walls." In short, claim 61 triggers an assessment based upon the mechanical relationship between the probe and the walls. In contrast, the Auer patent, directed to an OCT system merely determines the distance relationship between the vessel walls but does not generate any sort of assessment based upon this information as claimed.

Thus for the foregoing reasons, it is believed that the present claims are patentably distinguishable over the applied references.

Claims 53-58 were rejected under 35 U.S.C. 102(b) as being anticipated by McGee *et al.* (US Patent No. 5,752,518). This rejection is respectfully traversed for the following reasons.

The McGee patent show a three-dimensional support structure that contacts the peripheral surface of the tissue. Specifically, the McGee patent is directed toward creating a fixed known relationship between the imaging element and the peripheral tissue.

In contrast, claim 53 takes an opposite approach. Specifically, the probe induces movement between itself and the walls of the blood vessel. As further described in dependent claim 56, the probe is actually designed to induce movement between the head and the vessel walls.

As such the system of the McGee patent actually works in an opposite fashion. Specifically, it uses a balloon-like structure to create a rigid relationship rather than inducing movement as claimed.

Thus, it is believed that these claims are distinguishable over the applied reference.

Claims 1-64 were rejected under 35 U.S.C. 102(e) as being anticipated by Marshik-Geurts *et al.* (US 2004/0024298). This rejection is respectfully traversed for the following reasons.

As explained above, the key notion of the present invention is the recognition that catheter head motion can be exploited. As detailed in the instant published application:

> **[0011]** The present invention concerns an approach for improving the treatment and/or examination of vessels walls through fluid, such as blood. In the specific example, the invention is used for near infrared (NIR) spectroscopy. The invention can take advantage of the probe, such as catheter head, motion by identifying the points in time when the head is closest to the vessel wall or farthest from the vessel wall. Identification of this relative location enables meaningful spectral readings in larger vessels. In short, instead of trying to overcome motion (e.g., by centering the catheter), this approach takes advantage of motion by identify times when the catheter is closer to the vessel wall, in order to gather more useful spectral information or improve the efficacy of the treatment of the vessel walls.

The functionality is set forth in claim 1 for example in which the received optical signals are used to assess the vessel walls when the probe is determined to be close enough to the vessels walls to enable the assessment of the vessel walls. This assessment of the mechanical relationship between the probe and the walls is performed by analyzing the received optical signals.

Claims 53 and 61 are directed to inducing movement between the probe and the vessel walls.

Neither of these claimed features is described in the Marshik-Geurts Application. Thus, withdrawal of this rejection is requested.

It is believed that the present application is in condition for allowance. A Notice of Allowance is respectfully solicited. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

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